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(54) Drug eluting stent graft combination

(57) A device for delivery through a catheter to a desired site in a body vessel (2) for therapeutic treatment of a patient, comprises a pair of stents (11) having a compressed shape and an expanded shape, and which tend to expand resiliently from the compressed shape to the expanded shape such that when the stents are positioned at the desired site and immersed in a body fluid flowing past the desired site, the stents allow passage of body fluid. The device includes a cover (20) connecting said stents, said cover embedded with a coating wherein the coating is impregnated with a drug on its outer surface, such that when the stents expand against the surface of a lumen, it forces said drug against the lumen walls.

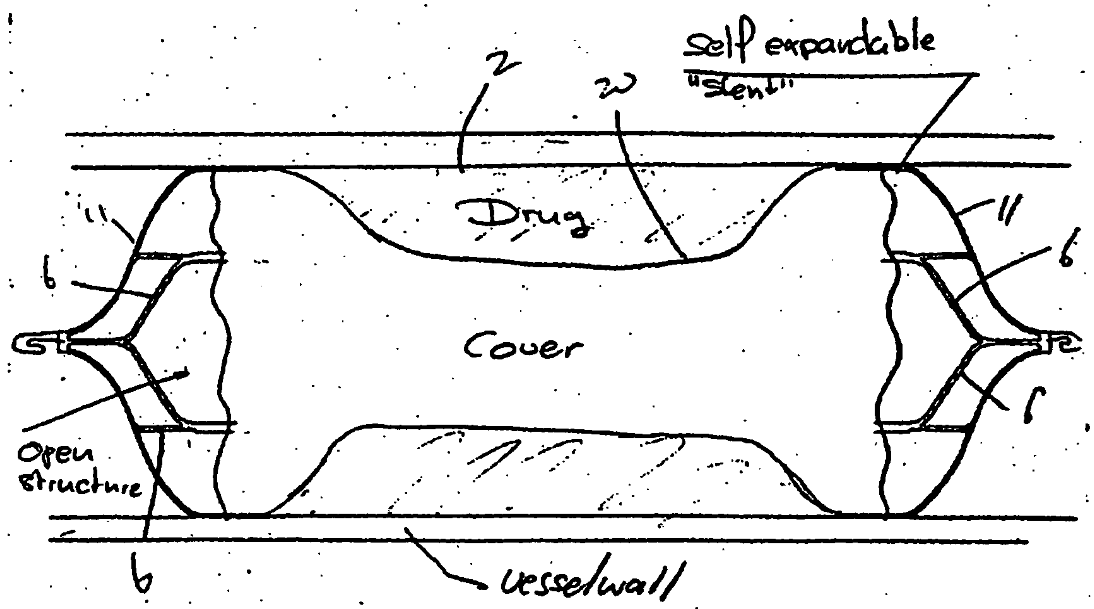

FIG. 8

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WI. USSN. 10/132,754

Description

[0001] The present invention relates generally to medical devices, and more particularly to a vascular stent graft and delivery system.

[0002] Vascular filters may be used for a variety of therapeutic applications, including implantable vena cava filters for capturing thrombus, or for distal protection during a vascular procedure.

[0003] The present invention relates to a system including a vascular filter or a stent, or a stent graft combination that can be placed inside a body passage or cavity, such as a blood vessel, through a catheter consisting of a tubular basic body with a distal end, a proximal end and a lumen extending in between the ends. The device can be received in a compressed state inside the lumen, and the catheter is provided with an ejection device that can be used to eject the vascular filter from the distal end of the catheter. The device may be implanted either permanently or temporarily.

[0004] Vascular filters, stents and stent-grafts are often made of an elastic or so-called "memory" material. Prior to actually positioning the vascular filter or other device according to the known technique inside the blood vessel, the device is arranged in a compressed state in the catheter. By means of an ejection member, the device may be pushed from the open distal tip of the catheter into the blood vessel.

[0005] Many prior vascular filters expand from the compressed state inside the catheter lumen to an enlarged or deployed state, when released or deployed at the desired site for treatment. Some vascular filters tend to resiliently expand to that deployed state, which facilitates ejection from the catheter. Also, this resilient outward pressing may resist longitudinal movement from the desired site or compressive external forces.

[0006] It is also possible, however, that the resilient expansion by a filter may cause it to push off in a resilient manner against the distal end of the catheter. This possible longitudinal pushing or jumping tendency may cause a vascular filter to rest in some location other than the desired site. Consequently, accurate positioning of the filter inside the blood vessel may require some measure of skill.

[0007] Accordingly, it is desirable to provide a vascular filter capable of being more easily positioned accurately, and which tends to proceed smoothly and predictably during deployment.

[0008] The present invention therefore provides a vascular filter for use with a catheter to introduce the filter, wherein a brake is provided. The brake acts between the filter and catheter which may tend to control ejection by means of engaging the lumen. This engagement may of course be frictional, and the brake may be provided on the filter or the catheter, or may consist of cooperating components on both filter and catheter.

[0009] With a vascular filter and catheter system according to the present invention, an accelerating force exerted by the vascular filter on the distal tip of the catheter can be resisted or even negated by the brake. The brake preferably frictionally opposes the movement of the filter out of the catheter. Consequently any expansive accelerating force exerted during ejection of the filter is controlled, at least any particular expansive force which may cause an unexpected longitudinal advance in relation to the distal tip of the catheter.

[0010] The brake may have any of a number of embodiments, as will be discussed in the detailed explanation below which are given by way of example. For example, the brake may have been biassed, or the brakes may form a unit with the filter, or may act in unison with additional brakes.

[0011] In an alternate embodiment of the present invention, the vascular filter, stent or graft is covered with an impermeable cover, so as to be able to deliver a drug to the wall of the lumen situated between the stent and the lumen.

[0012] Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is an external perspective view of a vascular filter and catheter system, arranged according to the principles of the present invention and in a position of use;

Figure 2 and 3 are partial perspective views of a vascular filter and catheter system according to one embodiment of the present invention, showing operation of a braking system;

Figure 4 is a perspective view of a vascular filter, showing another embodiment of the present invention;

Figure 5 is a partial perspective view of a vascular filter and catheter system arranged according to the principles of the present invention, after the filter has been ejected from the catheter;

Figure 6 is a perspective view of a vascular filter, according to another embodiment of the present invention;

Figure 7 is a partial perspective view of the vascular filter and catheter system of Figure 6, after the filter has been ejected from the catheter; and

Figure 8 is a plan view of an alternate embodiment of a stent or filter of the present invention with a coating attached to its centre.

[0013] Referring to the drawings, Figure 1 shows a vascular filter 1 which has been introduced into a blood vessel 2 by means of a catheter 3, which is substantially hollow. In the distal tip 4 of the catheter 3, at least one vascular filter was initially arranged in a compressed state. As an alternative (not illustrated), it is also possible that the filter is pushed along the entire length of the catheter from its proximal end to its distal end, after the catheter distal end has been advanced to the desired position. Preferably the filter is packed, in a compressed

state, in transport packaging forming a covering. The vascular filter may be ejected from the distal tip 4 of the catheter 3 by means of a pushing wire 5 and introduced into the blood vessel. Due to release from the radially compressive force imposed by the lumen at the distal tip 4 of the catheter 3, the vascular filter 1 will tend to expand resiliently to obtain an expanded shape.

[0014] The vascular filter illustrated here comprises a number of ribs 6 extending in an axial direction in relation to the blood vessel 2 and along the internal wall hereof. These ribs 6 form an elongated body member. On either side of the ribs 6, filters 7 have been arranged each forming a grid shape. Liquid inside the blood vessel can pass through in an unimpeded fashion, but thrombus will tend to be intercepted by one of the two filters 7.

[0015] An advantage of this configuration is that it provides two chances at intercepting thrombus moving inside the blood vessel. In addition, due to the configuration of the ribs 6 which extend along the internal wall of the blood vessel 2, there should be no free ends of ribs which might stick into the internal wall of the blood vessel 2. The configuration of the vena cava filter according to the present invention illustrated is consequently designed so as to minimize any distress or damage to the blood vessel inside of which it has been arranged. As filters 7 have been arranged on either side of the ribs 6, and consequently a symmetrical shape has been obtained, there is no difference in the performance of the filter regarding the direction from which this vascular filter 1 has been placed inside the blood vessel 2.

[0016] As has been illustrated here clearly, the grid shape of each of the filters 7 is such that each of the ribs 6 is connected with a number of the components of these filters. Furthermore, each of the ribs 6 is connected with both filters 7 on either side. Due to this configuration, an added safety feature is that one of the ribs 6 or a component of one of the filters 7 may even break without a part of the filter 1 separating as a consequence.

[0017] In addition, tipping over or misalignment of either filter is less likely due to the more or less tubular shape into which the ribs 6 have been arranged, so that positioning of the vascular filter 1 inside the blood vessel 2 can take place with unprecedented stability and reliability.

[0018] The vascular filter 1 is preferably made of a very resilient material, like nitinol. Following ejection from the distal tip 4 of the catheter 3, filter 1 can expand and will be wedged against the internal wall 8 of the blood vessel 2.

[0019] In accordance with embodiment of the present invention shown in Figure 1, two projections 9 form a resilient brake, arranged close to the proximal end of the vascular filter 1. These resilient projections 9 serve in particular to control ejection of the proximal section of the filter 1.

[0020] The projections 9 push against the inside of the catheter lumen close to the distal end of the catheter 3. The proximal filter 7 may tend to exert a force on the distal edge of the catheter 3 during ejection of the filter 1. In this way the projections 9 slow down the rate of expansion, and thus control the expansive force of the filter 7. Thus, accuracy when positioning a vascular filter according to the present invention may be improved.

[0021] In the embodiment shown in Figures 2 and 3, the projections 9 have been biassed and extend in an outward radial direction in relation to the proximal end section of the filter 1, so that they push against the internal wall of the catheter 3, before escaping from the catheter themselves. These outwardly directed projections 9 consequently cause a braking force on the internal wall of the catheter 3, which is also directed outwards, so that control of the ejection of the filter 1 is effected.

[0022] The projections 9 form a unit with the filter 1, in the sense that each of the projections 9 has been made of material from the filter 1 located in between closely arranged cuts 10. The strips of material from the cuts 10 have subsequently been biassed.

[0023] The filter 1 shown in the Figures has been made of a cylindrical unit. As an alternative, the filter may have been made from a plate-like unit or from an assembly of riblike elements. Other options are possible as well. The filter may have been made of a resilient material, such as nitinol, which expands into the filter 1 with the shape illustrated here, following ejection of the cylindrical body 1'. As an alternative or as an addition, different types of memory materials, or other shape-memory metals, may be used.

[0024] The projections 9 are positioned radially opposite each other near to the proximal end of the filter 1, so that as a consequence a more uniformly distributed force is exerted on the internal wall of the catheter 3. To this end also, more than two projections 9 may be employed. In Figure 2, the action of the projections 9, which push from the proximal end of the filter 1 against the internal wall of the distal end 4 of the catheter 3, has been illustrated schematically. As has already been mentioned before, this braking effect is preferably present especially during the release and expansion of the proximal filter 7 of the vena cava filter 1 according to the present invention. The projections 9 tend to slow down the ejection speed of the vascular filter 1, which is caused by elements of the proximal filter 7 pushing off against the extreme edge of the catheter 3 at the distal end hereof.

[0025] Figure 3 shows the situation illustrated in Figure 2 during a slightly later stage, and it is clear that the projections 9 pushed against the internal wall of the catheter 3 with a certain force. This situation is evidenced by confirming that the projections 9 protrude more than the internal dimensions of the catheter 3, in the state illustrated in Figure 3. The compression of the projections 9 illustrated in 2 consequently ensures that a braking force is exerted on the internal wall of the cath-

eter 3, which tends to control expansion of the proximal filter 7.

[0026] In the embodiment of the vascular filter 1 according to the present invention illustrated in Figure 4, the brake is formed as a single loop 11. The loop 11 is resilient in the sense that it has a tendency to expand from the state drawn with continuous lines, in the direction indicated by arrow A, into the state drawn with dotted lines. In Figure 4, the loop 11 has been illustrated in a state which corresponds to transportation inside the catheter 3 to the desired position. In contrast, the state of the loop 11 indicated with dotted lines corresponds to the relaxed situation, in which the vascular filter 1 has been ejected into the blood vessel. This last situation has been illustrated in greater detail in Figure 5, in which the vascular filter 1 and the proximal filter 7 with its loop 11 have expanded in a controlled manner.

[0027] It should be noted that by the time that the bending points 12 of the loop 11 pass the extreme distal edge of the catheter 3, the majority of the vascular filter, and in particular proximal filter 7, will have already secured itself against the wall of the blood vessel. Any longitudinal force due to expansion of the loop 11, after the bending points 12 have been ejected beyond the distal tip of the catheter 3, is consequently cushioned by the proximal filter 7 being stabilized inside the blood vessel 2.

[0028] One advantage of the embodiment of a vascular filter according to the present invention illustrated in the Figures 4 and 5 is that the loop 11 may be used to later remove the vascular filter 1. Loop 11 can thus serve as a target for a hook-shaped extraction element, in order to remove the vascular filter 1. The hook-shaped extraction body (not shown) may engage the loop 11, and pull the entire vascular filter 1 back into a catheter enveloping the extraction element.

[0029] After reading the above, many possible embodiments which may be used to control the ejection speed during expansion of certain components, other embodiments and features will occur to one of ordinary skill in the field. It is for instance possible to use a vascular filter which has a different shape than the one described above. It is also possible to use a more conventional vascular filter without the double filter-function. The vascular filter also does not need to comprise ribs extending in an axial direction in relation to the blood vessel.

[0030] Also, one or more removal members may be added at the distal end of the vascular filter, which may have been embodied in the shape of a hook or a loop. Such a removal member can be gabbed from the other side or the distal side such that removal of the filter is possible.

[0031] Referring further to the drawings, in Figure 8 a pair of vascular filters or stents 11 according to the present invention are illustrated. In the situation illustrated, the vascular filters 11 have just been introduced into a blood vessel 2 by means of a catheter 3, which is substantially hollow. In the distal tip 4 of the catheter 3, at least one vascular filter was initially arranged in a compressed state. As an alternative (not illustrated), it is also possible that the filter or stent is pushed along the entire length of the catheter from its proximal end to its distal end, after the catheter distal end has been advanced to the desired position. Preferably the filter is packed, in a compressed state, in transport packaging forming a covering. The vascular filter may be ejected from the distal tip 4 of the catheter 3 by means of a pushing wire 5 and introduced into the blood vessel. Due to release from the radially compressive force imposed by the lumen at the distal tip 4 of the catheter 3, the vascular filter or stent 11 will tend to expand resiliently to obtain an expanded shape.

[0032] The stent 11 illustrated here comprises a number of ribs 6 extending in an axial direction in relation to the blood vessel 2 and along the internal wall hereof. These ribs 6 form an elongated body member. Due to the configuration of the ribs 6 which extend along the internal wall of the blood vessel 2, there should be no free ends of ribs that might stick into the internal wall of the blood vessel 2. In addition, tipping over or misalignment of either filter is less likely due to the more or less tubular shape into which the ribs 6 have been arranged, so that positioning of the vascular filter 1 inside the blood vessel 2 can take place with unprecedented stability and reliability.

[0033] The vascular filter or stent 11 is preferably made of a very resilient material such as a shape memory alloy, especially nitinol. Following ejection from the distal tip 4 of the catheter 3, filter 1 can expand and will be wedged against the internal wall 8 of the blood vessel 2. The stents 11 contain between themselves a cover 20. This cover 20 is made of any conventional graft material, especially with low friction characteristics, for example a polyester such as that sold under the trade mark Dacron, or a fluorinated polyolefin, especially a polytetrafluoroethylene such as that sold under the trade mark Teflon. Importantly, it is envisioned that the cover 20 is impregnated with a drug coated controlled release polymer, so that a therapeutic amount of the drug can be released into the wall of the lumen. Some exemplary drugs that are useful are rapamycin, paclitaxel, and any analgesic such as acetaminophen. The polymer coating techniques that are useful to embed the coating into the cover 20 are known, such as those disclosed in WO-A-01/87342.

Claims

1. A device for delivery through a catheter to a desired site in a body vessel for therapeutic treatment of a patient, comprising:

    a pair of stents having a compressed shape and an expanded shape, and the stents tending to

resiliently expand from the compressed shape to the expanded shape, such that when the stents are positioned at the desired site and immersed in a body fluid flowing past the desired site, the stents allow passage of body fluid; and a cover connecting said stents, said cover embedded with a coating wherein the coating is impregnated with a drug on its outer surface, such that when the stents expand against the surface of a lumen, it forces said drug against the lumen walls.

2. The device as set forth in claim 1, wherein at least a portion of the stents comprises a shape memory alloy.

3. The device as set forth in claim 1, wherein said coating comprises a low friction polymer, preferably a fluorinated polyolefin.

4. The device of claim 1 wherein the stents are self-expanding.

5. The device of claim 1 wherein the stents have a pair of ends and a centre, wherein the centre has a lower self expanding force than the ends, so that the ends expand against the wall surface and leave the drug on said coating trapped against the centre of the stent.

6. The device of claim 6 wherein the coating a low friction polymer, preferably a fluorinated polyolefin.

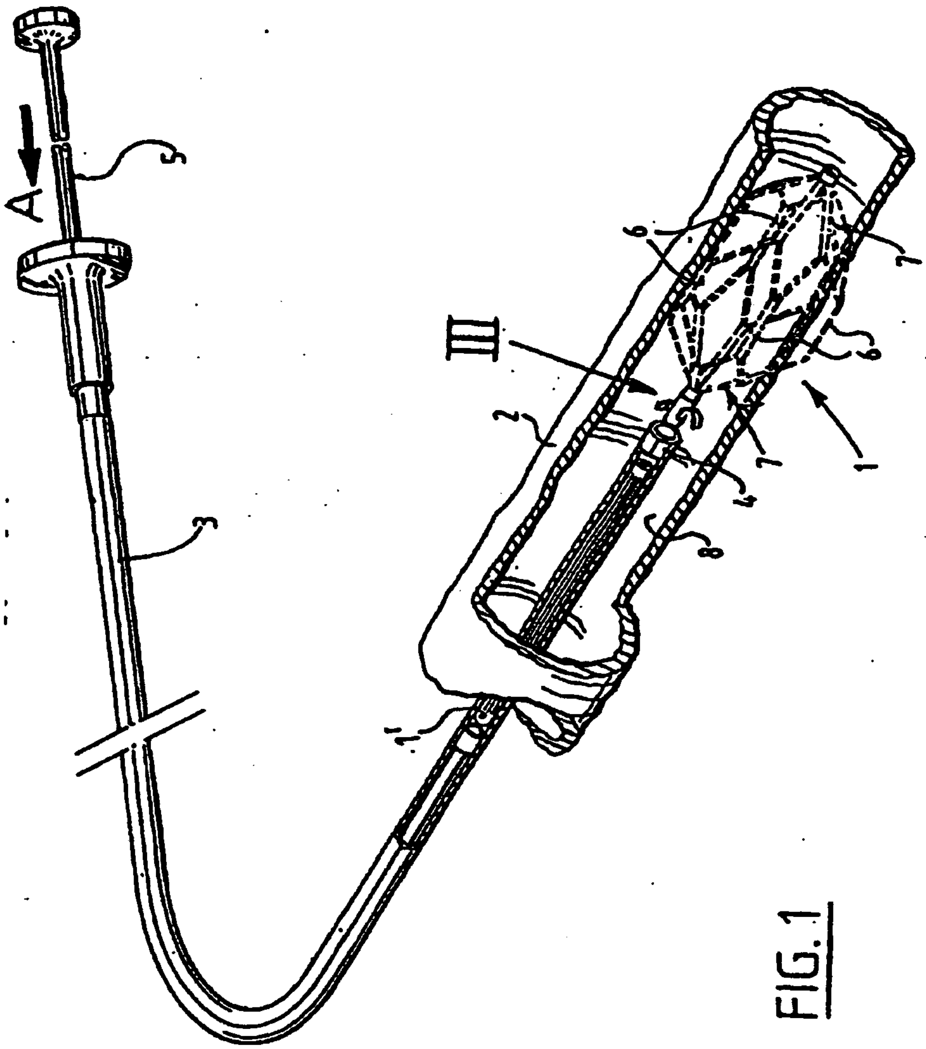

FIG.1

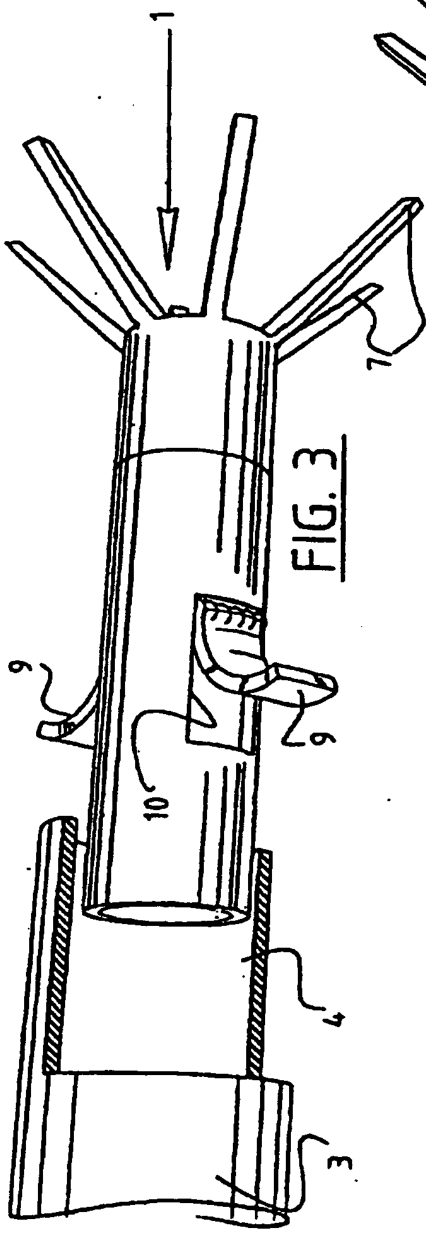

FIG. 3

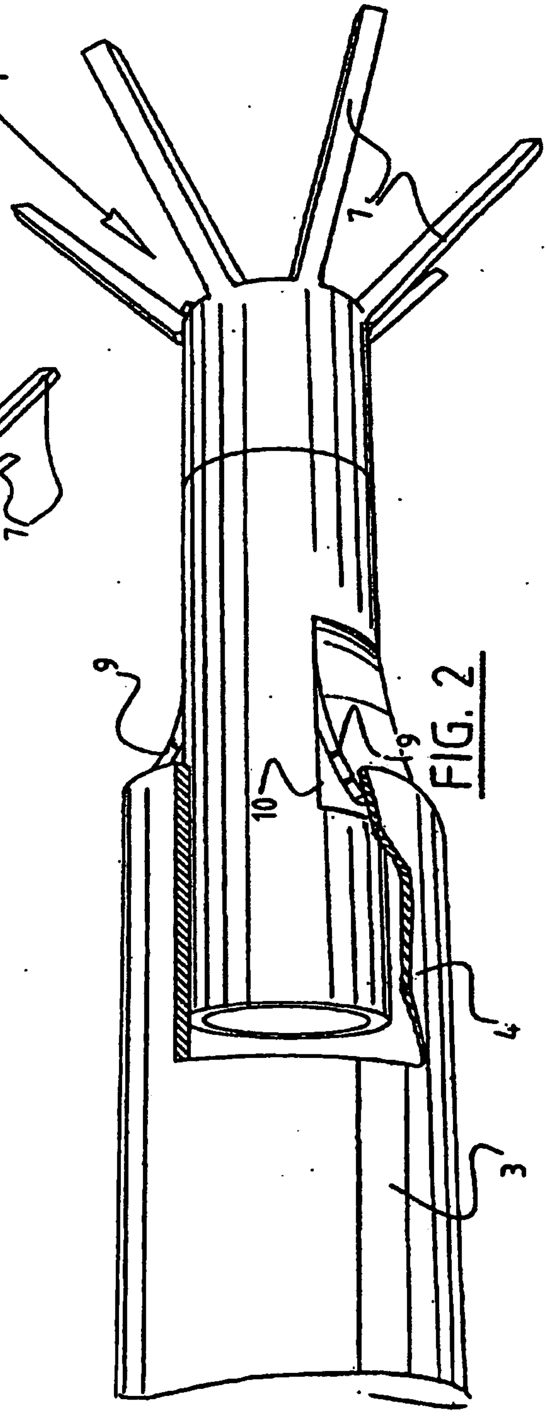

FIG. 2

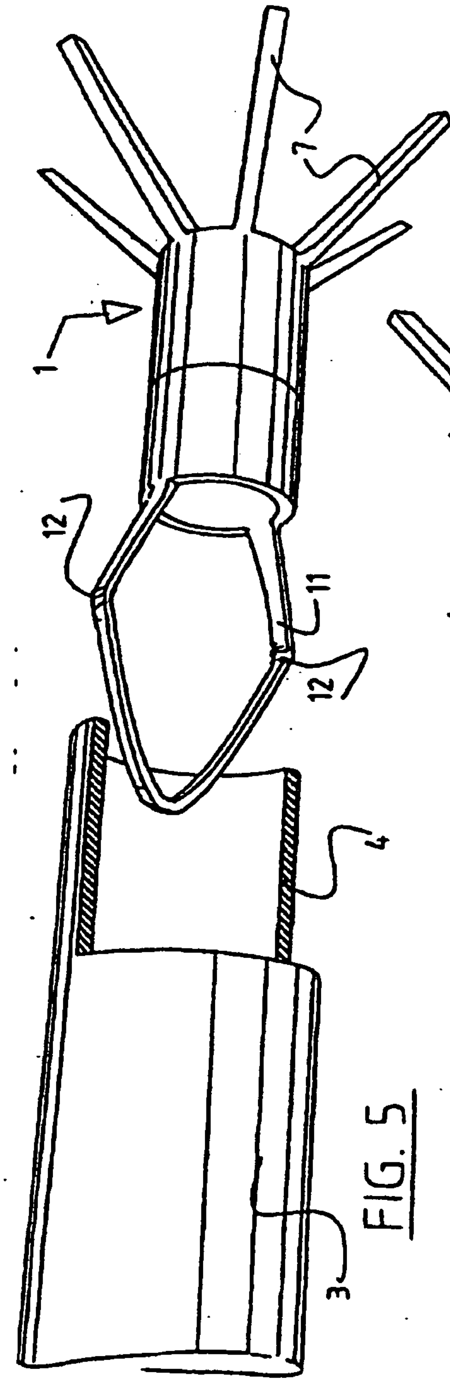

FIG. 5

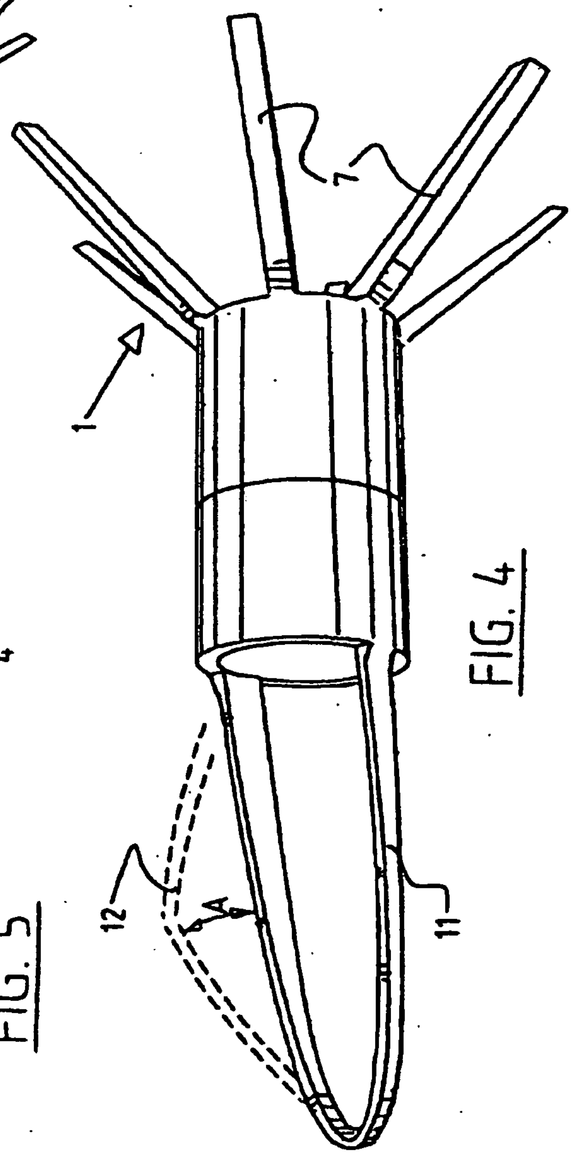

FIG. 4

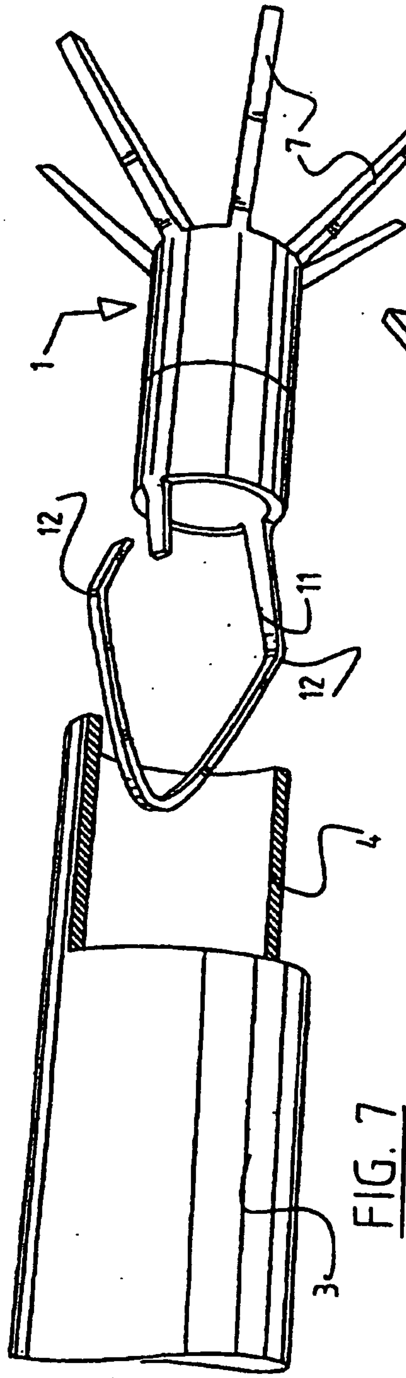

FIG. 7

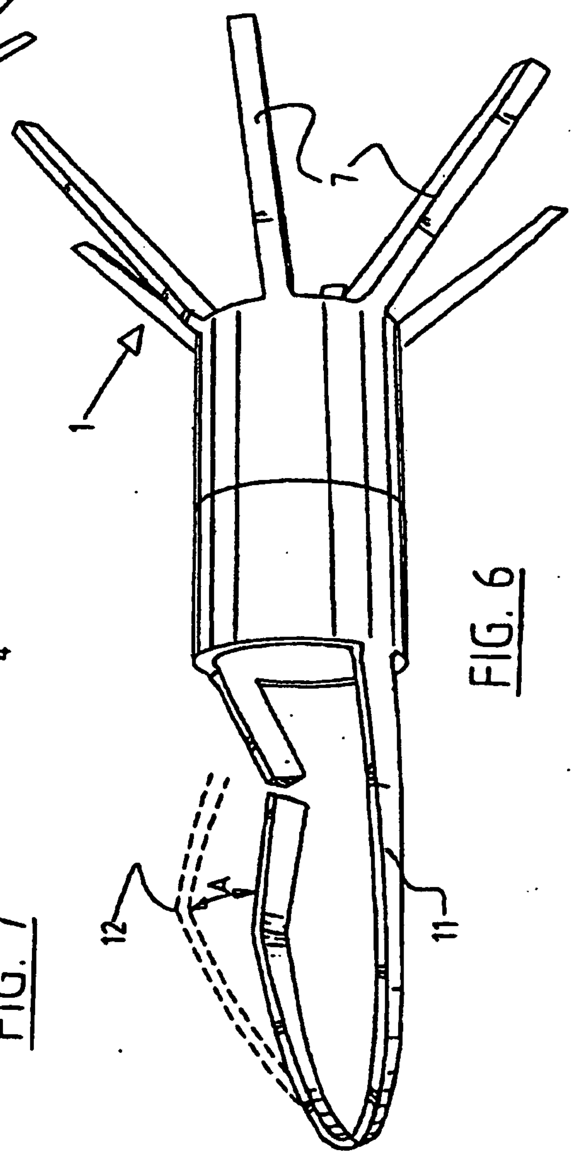

FIG. 6

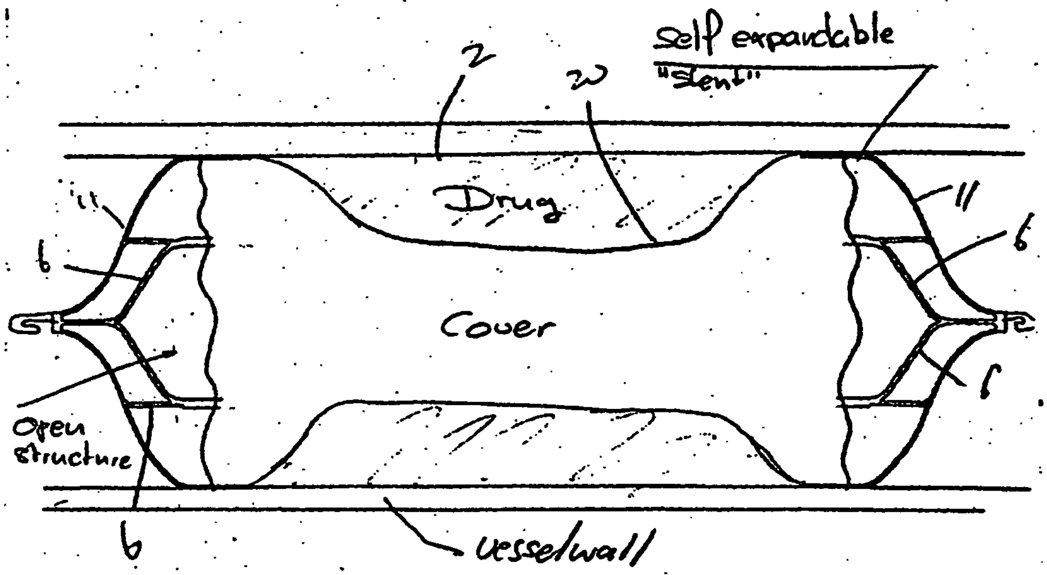
self expandable "stent"
2
2W
Drug
11
6
Cover
Open structure
vesselwall

FIG. 8